

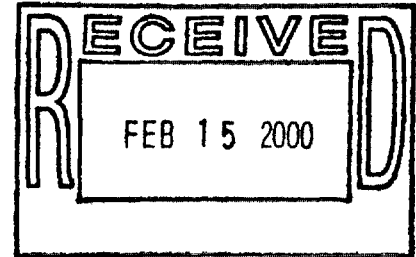
# EMORD & ASSOCIATES, P.C.

BURKE PROFESSIONAL CENTER  
5282 LYNNGATE COURT  
BURKE, VIRGINIA 22015

1050 SEVENTEENTH STREET, N.W.  
SUITE 600  
WASHINGTON, D.C. 20036

PHONE: (202) 466-6937 • FAX: (202) 466-6938  
WEB SITE: [www.emord.com](http://www.emord.com)  
E-MAIL: [emordall@erols.com](mailto:emordall@erols.com)  
February 11, 2000

1778 '00 FEB 29 P2:15



## VIA UPS NEXT DAY AIR

Dr. Elizabeth Yetley  
Office of Special Nutritionals (HFS-450)  
Food and Drug Administration  
200 C Street, S.W.  
Washington, D.C. 20204

### *Re: Fulfillment of Reporting Obligation Under 21 U.S.C. § 343(r) and 21 CFR § 101.93*

Dear Dr. Yetley:

Rx Vitamins, Inc.,<sup>1</sup> by counsel and in accordance with 21 U.S.C. § 343(r) and 21 C.F.R. § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Rx Vitamins, Inc. retains scientific documentation supporting the statements.

#### 1. Supplement Brand Name (ingredient)

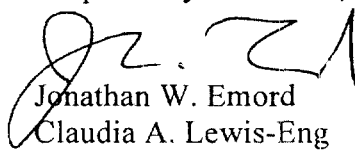
Valerian Root (valerian root)

#### Text of Statements of Nutritional Support

*For Relief of Occasional Sleeplessness*

In accordance with 21 U.S.C. § 343(r)(6) and 21 C.F.R. § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."**

Respectfully submitted,

  
Jonathan W. Emord  
Claudia A. Lewis-Eng  
Steven W. Allis

97S - 0162

Attachment

<sup>1</sup> The address for Rx Vitamins, Inc. is 200 Myrtle Boulevard, Larchmont, NY 10538.

LET

69245  
4981

Feb. 8. 2000 5:46PM 914 834 5265

No.4842 P. 3/3

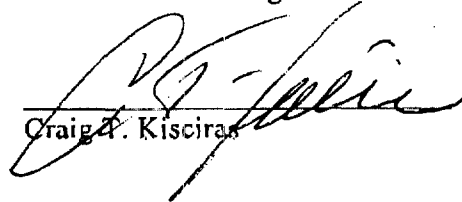
Certification

I, Craig T. Kisciras, General Manager of Rx Vitamins, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Rx Vitamins, Inc. has substantiation that the statements are truthful and not misleading.

Executed on:

FEBRUARY 8, 2000

Craig T. Kisciras

A handwritten signature in dark ink, appearing to read "Craig T. Kisciras", written over a horizontal line.